

**REMARKS**

Applicants initially wish to thank Examiner Yu for the telephone interview conducted with Applicants' representative, Jeffrey Tidwell, on July 21, 2003.

Claim 1 is amended herein to recite that n in the compounds of formula (I) is a number such that the number average molecular weight of the compounds ranges from 150 to 200,000, instead of from 100 to 200,000. Support for this amendment is found in Applicants' originally filed specification at least at p. 6, line 13, and original claims 10, 15, 16, 36, 41, and 42, wherein a number average molecular weight of 150 is recited. As such, no new matter has been added.

Claim 14 has been amended herein to correct an obvious, typographical error in the dependency of the original claim. Specifically, original claim 14 recited a process "according to claim 14 . . . ." It is amended herein to recite a process "according to claim 13 . . . ." Support for this amendment is found in Applicants' originally-filed specification at least at p. 6, line 11. In addition, the present amendment corrects an error that would be recognized as obvious by one skilled in the art, and the correction made herein would be recognized as appropriate. As such, no new matter has been introduced. See M.P.E.P. § 2163.07(II).

**I. Disposition of the Claims**

Claims 1-59 are pending in the instant application. Claims 31-59 were withdrawn, with traverse, pursuant to a restriction requirement. Claims 1-30 stand rejected under 35 U.S.C. § 112, second paragraph, 35 U.S.C. § 102(b), and 35 U.S.C. § 103(a). Each of these rejections is discussed further below.

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**II. Rejection under 35 U.S.C. § 112, second paragraph**

The Examiner has maintained the rejection of claims 1, 4, 5, 10, 12, 13, 16, 17, and 21-24 under 35 U.S.C. § 112, second paragraph as indefinite. In particular, it is the Examiner's position that Applicants' use of the term "hydrocarbon-based radical," which was defined to include alkyl chains that may contain heteroatoms, is "repugnant to the usual meaning of that term." Office Action dated April 23, 2003, p. 2, lines 11-17. Applicants respectfully traverse the rejection for the reasons already of record (see, e.g., Response filed January 30, 2003, p. 1, line 18 - p. 3, line 6) and for the additional reasons below.

The test of whether a claim meets the requirements of definiteness under 35 U.S.C. § 112, second paragraph, is whether the claim language is clear and precise, not whether more suitable language or modes of expression are available. Such an inquiry must take into consideration: 1) the content of the disclosure; 2) the teachings in the art; and 3) the interpretation that would be given to the claim by one skilled in the art. A claim should not be rejected because an Examiner prefers language other than that used by the applicant. M.P.E.P. § 2173.02. Furthermore, an applicant is permitted to use his own terminology, as long as it can be understood. M.P.E.P. § 608.01(g).

Applicants have used the term "hydrocarbon-based radical" in a consistent manner throughout the originally-filed specification and in the present claims. The Examiner must give weight to the way in which the claim terms are used in the specification as well as the claims. See, e.g., *SciMed Life Sys., Inc. v. Advanced Cardiovascular, Inc.*, 242 F.3d 1337, 58 USPQ2d 1065 (Fed. Cir. 2001). In this instance, the Examiner has failed to do so and instead has just stated that one skilled in

the art would find Applicants' use of the term "repugnant to the usual meaning of that term." There is no evidence of record to indicate that one skilled in the art, reading the instant specification, would be confused as to the meaning of the term "hydrocarbon-based radical," or would find it meaning "repugnant." As such, Applicants respectfully submit that the Examiner has failed to meet her burden of providing objective evidence that the term at issue is unclear or repugnant to its usual meaning. Therefore, the rejection under 35 U.S.C. § 112, second paragraph, is improper and Applicants respectfully ask that it be withdrawn.

Additionally, Applicants respectfully submit that the term "hydrocarbon-based radical" is not unclear because one of ordinary skill in the art reading the term would immediately understand that the term "hydrocarbon" is modified by the term "based." Furthermore, Applicants respectfully submit that the term "based" has been used in a manner that is consistent with its ordinary meaning, one that a person of ordinary skill in the art would ascribe to it. For example, the *American Heritage College Dictionary* defines "based" as "[t]o form or provide a base for," or "to find a basis for." *American Heritage College Dictionary*, 3<sup>rd</sup> Ed., 1997, p. 113. In turn, the term "base" is defined as "[t]he lowest or bottom part," a "supporting part or layer," and a "basic or underlying element; an infrastructure." *Id.* With these definitions in mind, it is clear that Applicants have used the term "based" according to its ordinary meaning to mean an infrastructure that can be further modified. In other words, one of ordinary skill in the art would immediately understand that the term "hydrocarbon-based radical" means radicals in which the infrastructure is made of carbon and hydrogen and which infrastructure may be further modified. The modifications that are intended to be encompassed in

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Applicants' claims are discussed in detail in the originally-filed specification at least at p. 4, lines 11-15; p. 6, lines 3-7 and lines 17-20; and at least original claims 1-5, 12, 13, 34, 35, 36, 38, 39, 42, and 43. As such, it would be amply clear to one of ordinary skill in the art what Applicants' mean when the term "hydrocarbon-based radical" is used in the present claims. Therefore, the present claims containing the term "hydrocarbon-based radical" more than meet the definiteness requirement of 35 U.S.C. § 112, second paragraph, and Applicants respectfully ask that the rejection be withdrawn.

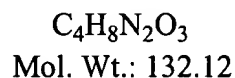
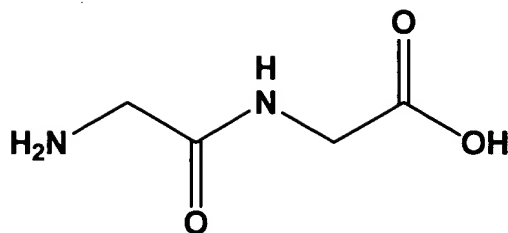
### **III. Rejection under 35 U.S.C. § 102(b)**

The Office has maintained the rejection of claims 1-30 under 35 U.S.C. § 102(b) in view of *Yu* (U.S. Pat. No. 5,886,041). In particular, it is the Examiner's position that *Yu* discloses compositions for the treatment of skin disorders, such as acne, that comprise "amphoteric compounds such as dipeptides and polypeptides." Office Action dated October 22, 2002, p. 3, lines 11-15. Furthermore, the Examiner contends that *Yu* discloses a specific dipeptide, glycine-glycine, that reads on the compounds of formula (I). *Id.* Applicants respectfully traverse this rejection for the reasons of record (see, e.g., Response dated January 30, 2003, p. 3, line 7 - p. 4, line 13) and for the additional reasons found below.

Applicants have amended independent claim 1 herein to recite that in the compounds of formula (I), *n* is a number greater than 1 such that the number average molecular weight of the compound ranges from 150 to 200,000. The structure of glycine-glycine, along with its associated molecular formula and weight, are shown below.

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As can be seen, the molecular weight of glycine-glycine is 132.12. Amended claim 1 requires that the value of (n) in the compounds of formula (I) be chosen such that the number average molecular weight of the compounds ranges from 150 to 200,000. As such, glycine-glycine, with a molecular weight of 132, is outside the scope of amended claim 1. Furthermore, the *Yu* reference provides no other compounds that fall within the scope of amended claim 1. As such, the current rejection of the claims under 35 U.S.C. § 102(b) is now moot and Applicants respectfully ask that it be withdrawn.

#### IV. Rejection under 35 U.S.C. § 103(a)

The Office has maintained its rejection of claims 1-30 under 35 U.S.C. § 103(a) in view of *Yu*. In particular, it is the Examiner's position that *Yu* teaches the use of dipeptides for the treatment of skin disorders such as acne. The Examiner admits, however, that *Yu* "lacks examples for the full scope of *Yu*'s teachings." Office Action dated October 22, 2002, p. 4, lines 3-11. Despite this deficiency, the Examiner contends that it would have been obvious to modify the teachings of *Yu* by using "a variety of dipeptides, tripeptides, and short-chain polypeptides based on the teachings of *Yu* that a variety of components are effective." *Id.* at p. 4, lines 12-16. Applicants

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respectfully traverse this rejection for the reasons of record (see, e.g., Response filed January 30, 2003, p. 4, line 14 - p. 6, line 9) and for the additional reasons below.

First, the *Yu* reference teaches that "peptides" and "polypeptides" in general can be used in the disclosed compositions in combination with hydroxyacids. But, the *Yu* reference provides limited guidance to one skilled in the art in terms of what types of peptides or polypeptides can be used in the disclosed compositions. In fact, the only guidance the *Yu* reference provides is the list of dipeptides, tripeptides, and polypeptides listed in col. 5, lines 7-15. As discussed with respect to the current rejection under 35 U.S.C. § 102(b), none of the dipeptides, tripeptides, or polypeptides disclosed in *Yu* fall within the current claims as amended. Most importantly, of the "dipeptides" and "tripeptides" listed in *Yu* at col. 5, lines 7-15, only one (glycine-glycine) is composed of alpha-amino acids as required by compounds of formula (I) found in the instant claims. As discussed above, the instant claims have been amended herein to exclude peptides with a molecular weight less than 150, thereby taking the glycine-glycine dipeptide outside the scope of the claims.

Second, Applicants respectfully disagree with the Examiner's contention that "the scope of formula (I) encompasses any amino acid." Office Action dated April 23, 2003, p. 3, line 20-22 (emphasis added). On the contrary, only a subset of the natural alpha-amino acids are encompassed within the compounds of formula (I). For example, in the compounds of formula (I), the side-chain of the amino acid monomers, represented by  $R_2$ , is chosen from a group of substituents including hydrogen, linear and branched  $C_{1-8}$  hydrocarbon based radicals,  $-CH_2C_6H_5$ ,  $-CH_2C_6H_4OH$ ,  $-CH_2OH$ ,  $-CH(OH)CH_3$ , and  $-(CH_2)_tNH_2$ , wherein  $t$  is 3, 4, or 5. This selection of side-chains encompasses only 10 of

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the 20 natural alpha-amino acids (glycine, alanine, valine, leucine, isoleucine, phenylalanine, serine, threonine, tyrosine, and lysine). Furthermore, the compounds of formula (I) include a multitude of compounds comprising non-natural amino acids, none of which are even taught or suggested by *Yu*.

The *Yu* reference provides no teaching or suggestion that would have guided one skilled in the art to prepare the compounds of formula (I), containing only a subset of the side chains present in the natural, alpha-amino acids familiar to one skilled in the art. Furthermore, nothing in the *Yu* reference remotely teaches or suggests that the disclosed compositions can contain polypeptides composed of non-natural, alpha-amino acids. As such, the general teaching that the compositions disclosed by the *Yu* reference can contain "dipeptides," "tripeptides," and "polypeptides" is not sufficient to render the instantly claimed compositions obvious under 35 U.S.C. § 103(a).

Rather, the facts of the instant case are similar to those in *In re Baird*, in which the Court of Appeals for the Federal Circuit held that the disclosure of a genus does not necessarily render obvious the species contained within it. 16 F.3d 380, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994). *Also see In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). In this case, the disclosure in *Yu* of "dipeptides," "tripeptides," and "short-chain polypeptides," including peptides composed of amino acids other than alpha-amino acids, would not render obvious the instant compositions comprising compounds comprising alpha-amino acids. Furthermore, the compounds of formula (I) contain compounds comprising non-natural, alpha-amino acids, none of which are taught or suggested by *Yu*. As such, the disclosure in *Yu* would not have rendered the instant

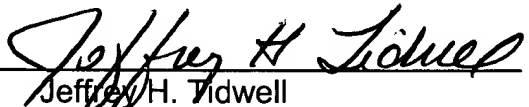
claims obvious under 35 U.S.C. § 103(a). Therefore, Applicants respectfully request that the rejection of the present claims be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
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Dated: July 23, 2003

By:   
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